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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/538,036	03/29/2000	Christophe P. G. Gerald	57155-D/JPW	6128
7590 06/04/2004			EXAMINER	
John P White Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036			MURPHY, JOSEPH F	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/538,036

**Applicant(s)**

GERALD ET AL.

**Examiner**

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 218-235 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 218-234 is/are allowed.
- 6) ☒ Claim(s) 235 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Formal Matters***

Claims 218-235 are pending and under consideration.

### ***Response to Amendment and Arguments***

Applicant's arguments filed 3/25/2004 have been fully considered but they are persuasive in part.

The rejection of claim 26 under 35 U.S.C. 112, first paragraph, because the specification, which is enabling for a full length human NPFF2 protein of SEQ ID NO: 1, does not reasonably provide enablement for a monomer with a P-S6 region which is 80% identical to human NPFF2 P-S6 region, or a monomer which specifically binds to SEQ ID NO: 1, or a human NPFF2 amino acid sequence, has been rendered moot by cancellation of the claim, and is thus withdrawn.

The rejection of claim 26 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, has been rendered moot by cancellation of the claim, and is thus withdrawn.

The rejection of claim 26 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been rendered moot by cancellation of the claim, and is thus withdrawn.

Remaining issues are set forth, *infra*.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 235 stands rejected under 35 U.S.C. 102(b) as being anticipated by Lukacs et al. (1992), for reasons of record set forth in the Office Action of December 8, 2003.

The rejection of record set forth that the Lukacs et al. reference teaches the preparation of a membrane preparation, i.e. endosomes, from CHO cells which comprise the CFTR protein.

Claim 235 is directed to a membrane preparation isolated from, *inter alia*, CHO cells. Claim 235 as written does not contain a limitation wherein the membrane preparation must comprise the encoded NPFF2 protein. Therefore, the membrane preparation of Lukacs et al. anticipates the membrane preparation of claim 235 in that it is isolated from CHO cells, and is thus identical to the instantly claimed membrane preparation.

Applicant argues that claim 235 is not anticipated by the teachings of Lukas et al. because the claim is indirectly dependent upon claim 218 that comprises the encoded NPFF2 protein. However, while claim 235 is dependent from claims reciting a host cell comprising a vector that comprises the nucleic acid encoding the NPFF2 receptor, claim 235 does not contain a limitation wherein the membrane preparation contains the encoded NPFF2 receptor. The claim only requires that the membrane preparation is prepared from a host cell comprising a vector comprising the NPFF2 encoding nuclei acid. It is possible to prepare a membrane preparation from a host cell comprising the NPFF2 nucleic acid without the membrane preparation

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comprising the NPFF2 receptor. A membrane preparation from a CHO cell that does not comprise the NPFF2 receptor, even if the CHO cell was transfected with the NPFF2 vector and expressed the protein, is not different from a membrane preparation prepared from a cell that never comprised the NPFF2 nucleic acid. Thus claim 235 is anticipated by the Lukacs et al. preparation.

***Conclusion***

Claim 235 is rejected.

Claims 218-234 are allowable.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
June 1, 2004



ELIZABETH KEMMERER  
PRIMARY EXAMINER